SECTION E - Letters to All Manufacturers and Users Notices from October 1999 to Present

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Centers for Disease Control
and Prevention (CDC)
National Institute for Occupationa
Safety and Health - ALOSH
1095 Willowdale Road
Morgantown, WV 26505-2888

December 7, 1999

NIOSH Respirator User Notice

The National Institute for Occupational Safety and Health (NIOSH) wishes to inform users of self-contained breathing apparatus (SCBA) that certain high-pressure aluminum seamless and aluminum composite hoop-wrapped cylinders made of aluminum alloy 6351-T6 are susceptible to sustained load cracking (SLC) in the neck and shoulder area. If such cracks are not detected during visual inspection, cylinder rupture can occur, especially during filling. These ruptures can result in serious injury, death, and/or property damage. The Institute is therefore recommending that these cylinders be given special attention in order to eliminate the risks associated with such cylinder ruptures. These affected cylinders are used on a number of NIOSH-approved SCBA and are available in a number of sizes and durations ranging from 5 to 30 minutes.

It is important to note that only a small percentage of cylinders made of aluminum alloy 6351-T6 have actually been found to exhibit sustained load cracking. Moreover, out of several million cylinders manufactured from this alloy by various companies, NIOSH and the US Department of Transportation (DOT) are aware of only 12 ruptures within the United States. Eleven of the 12 ruptures occurred during refilling. Six of these 12 ruptures involved SCBA cylinders while the others involved cylinders used for SCUBA diving, medical oxygen, or carbon dioxide storage. Forensic analysis has determined that most of these cylinders failed due to SLC failure. However, in some cases, evidence of other factors such as external mechanical damage was also present.

All six of the SCBA cylinders in question were manufactured by Luxfer Gas Cylinders. Luxfer discontinued the use of aluminum alloy 6351-T6 in the United States in1988, and Luxfer cylinders manufactured in the United States after this date are not believed to be susceptible to SLC failure. Therefore, Luxfer cylinders manufactured in the United States after 1988 are not subject to this notice.

The DOT specification for the suspect cylinders is DOT-3AL. Prior to 1989, aluminum alloy 6351-T6 was used in the manufacture of cylinders identified by the following DOT exemption numbers:

Seamless Aluminum Cylinders	Aluminum-lined Composite (hoop-wrapped) Cylinders
DOT-E 6498 DOT-E 7042 DOT-E 8107 DOT-E 8364 DOT-E 8422	DOT-E 7235 DOT-E 8023 DOT-E 8115

These DOT exemption numbers should be clearly marked on the cylinder label. The DOT has published additional information about this cylinder problem in Federal Register Notices dated October 18, 1999 (Volume 64, Number 200, pages 56243-56244) and July 26, 1994 (Volume 59, Number 142, pages 38028-38030).

The most recent SCBA cylinder rupture occurred at the Summerfield, North Carolina, Fire District on May 2, 1999. While no injuries were reported, the charging station in which the cylinder was enclosed sustained considerable damage. The cylinder was manufactured by Luxfer under DOT exemption DOT-E 6498, in June, 1977. Subsequent analysis revealed that cracks in the neck region of the ruptured cylinder were more than eight years old. The investigation further established that the cylinder had been leaking prior to the rupture.

The Institute has consulted with DOT, SCBA manufacturers, and Luxfer, and has determined that in order to reduce the risk of death, serious injury, or property damage, the following safety precautions should be taken with regard to all seamless aluminum DOT-3AL and composite aluminum hoop-wrapped cylinders manufactured of 6351-T6 alloy:

1. **Increase the frequency of internal visual inspections.** An internal visual inspection should be performed on an annual basis, as recommended by DOT. The internal visual inspection, which is performed by removing the cylinder valve, inserting a high-intensity light probe and an angled mirror into the cylinder and examining the inner surfaces of the cylinder, is useful in identifying SLC defects in the inner surfaces of the neck and shoulder area. This internal inspection should be performed by a qualified inspector in accordance with comprehensive inspection guidelines for high pressure aluminum cylinders. Examples of recognized inspection guidelines include the Compressed Gas Association (CGA) C-6.1 *"Standards For Visual Inspection of High Pressure Aluminum Compressed Gas Cylinders"*, and Volume 1 of *"Luxfer's SCBA Cylinder Visual Inspection Guide"*. Any discovered evidence of a crack, defect, or damage requires the cylinder to be removed from service. Some SCBA manufacturers have their own inspection guidelines.

2. **Inspections should be performed by qualified individuals.** A fire department or other SCBA user may choose to perform these annual inspections in-house, or may contract with a qualified outside inspector. In any case, individuals inspecting for evidence of SLC or any other cylinder damage or imperfection must be able to follow visual inspection guidelines competently and should be trained by accomplished instructors experienced in visual inspection of cylinders.

   A fire department or other SCBA user choosing to out-source the inspection process should verify the qualifications and capability of the contracted inspector. Internal visual inspection has been shown to be highly effective in the discovery of SLC defects. **However, these inspections are only effective when properly performed**. Therefore, emphasis should be placed on inspector training and diligence in the inspection process.

US DOT requires that hydrostatic retesting and requalification be conducted by registered agents who have been certified by the DOT and who have been issued a valid Retester's Identification Number (RIN) by the DOT Research and Special Programs Administration (RSPA). The recommended annual visual inspection does not have to be conducted by a DOT certified RIN holder. However, as stated above, the visual inspection should be conducted by someone who has been trained, qualified, and shown to be competent in conducting visual internal inspection.

3. **Submit cylinders for non-destructive testing at regular intervals between the required requalification testing.** While DOT requires the requalification (hydro-testing) of DOT-3AL seamless aluminum cylinders every 5 years, and of aluminum-lined composite (hoop-wrapped) cylinders every 3 years, it is recommended that cylinders be submitted for ultrasonic testing, eddy current testing, or some other form of non-destructive testing in between the normal required hydro-tests. Non-destructive testing should be performed only by qualified and competent inspectors who understand the proper use of such equipment. The qualifications of any cylinder inspector or tester should be verified prior to contract negotiations.

4. **Do not refill any cylinder that has lost internal pressure for no apparent reason.** Unexpected loss of cylinder pressure may be an indication that SLC defects have developed in a cylinder. Any cylinder that is found to have lost pressure for no apparent reason should be immediately removed from service, and an internal visual inspection should be conducted to evaluate the cylinder. This recommendation also applies to any cylinder, regardless of construction.

5. **Cylinders should only be refilled in a manner which limits risk to personnel and property.** It is recommended that all seamless aluminum DOT-3AL and composite aluminum hoop-wrapped cylinders manufactured of 6351-T6 alloy be filled or "topped off" inside a suitable enclosure or in a way that prevents injury and property damage. A number of compressor manufacturers, as well as other companies produce and market enclosed cylinder refilling stations designed for this purpose.

6. **Use proper cylinder filling equipment and procedures and refrain from fast-filling.** SLC growth occurs over several years, but such growth and the likelihood of cylinder rupture are accelerated when the cylinders are over-pressurized, filled without regulators and the proper filling apparatus, or fast-filled. As noted, 11 of 12 DOT-3AL cylinder failures have occurred during the filling process. The Luxfer recommended fill rate for DOT-3AL cylinders made of alloy 6351-T6 is below 600 psig per minute. Therefore, users should refrain from fast-filling cylinders constructed of alloy 6351-T6 aluminum.

   A just-filled cylinder should not feel warm or hot to the touch. The cylinder must never be filled to a pressure above the service pressure stamped on the cylinder.

7. **Check for valid re-test date before filling.** No cylinder, regardless of construction type, should be filled if it has exceeded the valid service life or re-test (re-qualification) dates specified by DOT.

Procedures on inspecting high pressure aluminum cylinders can be obtained by contacting:

Luxfer Gas Cylinders
Customer Service Department
3016 Kansas Avenue
Riverside CA 92507

(909) 684-5110 (phone)
(909) 781-6598 (fax)
www.luxfercylinders.com (Internet)

Compressed Gas Association
1725 Jefferson Davis Highway
Suite 1004
Arlington VA 22202-4102

(703) 412-0900, ext. 799 (phone)
(703) 412-0128 (fax)
www.cganet.com (Internet)

For further information, please contact Mr. Tim Merinar or Mr. Tom McDowell at NIOSH by calling (304) 285-5907 or by contacting the NIOSH Technical Information Hotline at 1-800-35-NIOSH.

Sincerely,

Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
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National Institute for Occupation
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December 22, 1999

NIOSH Respirator User Notice

Subject: CSE SR-100 Breathing Tube

The National Institute for Occupational Safety and Health (NIOSH) wishes to inform users of CSE Corporation SR-100 self-contained-self-rescuers (SCSRs) approved by NIOSH and the Mine Safety and Health Administration (MSHA), approval number TC-13F-239, of a problem found in some of these SCSRs which were manufactured prior to June 7, 1994, that could prevent them from providing effective protection.

The Mine Safety and Health Administration reported to NIOSH on December 8, 1999, that a miner who either donned, or attempted to don, an SR-100 SCSR during a brief electrical fire in a mine, suffered smoke inhalation requiring medical treatment at a hospital. A deteriorated breathing tube on the SR-100 SCSR that was opened by the miner prevented the unit from providing adequate protection from the smokey atmosphere. The SR-100 SCSR opened by the miner during the mine fire was manufactured in 1991.

In an effort to determine if this was an isolated incident, MSHA opened additional SR-100 SCSRs at the mine where the fire occurred and identified three (3) more SR-100 SCSRs containing breathing tubes in an unusable condition. Subsequently, three hundred twenty eight (328) SR-100 SCSRs originally issued to MSHA inspectors were opened by MSHA and NIOSH at NIOSH's Pittsburgh Research Laboratory on December 10, 1999. Of these three hundred twenty eight (328), six (6) more were found to have breathing tubes in an unusable condition. To date, ten (10) SR-100 SCSRs manufactured from 1990 through January 1993 have been found to have unusable breathing tubes. The breathing tube material was changed in June 1994 from natural rubber to silicone. None of the units manufactured after that date, containing the newer breathing tube material, were found to be in an unusable condition but there has been no finding at this time that the use of natural rubber caused the problem.

The cause of the problem observed on the older breathing tube material has not yet been conclusively determined. The manufacturer's preliminary determination is that exposure to temperatures above the recommended limit of 130° F. has caused deterioration of the breathing tubes. The breathing tube is enclosed within the sealed case of the unit, which may not be opened prior to actual use, and there have been no observable differences in the external condition of units found with an unusable breathing tube. Therefore, any CSE SR-100 SCSRs manufactured before June 7, 1994, may contain this critical safety defect and all are subject to corrective action to assure that they have not been similarly affected.

Users of CSE SR-100 SCSR devices manufactured prior to June 7, 1994, should, in accordance with availability, do one of the following as expeditiously as possible: 1) have the devices retrofitted by the manufacturer; 2) replace each device with a CSE unit manufactured after June 7, 1994; or 3) obtain other approved SCSRs.

The following manufacturers, listed in alphabetical order, produce MSHA/NIOSH approved SCSR devices.

CSE Corporation, telephone number, (800) 245-2224 or (412) 856-9200
Attention, Scott Shearer

Draeger, telephone number, (800) 858-1739 or 1741
Attention, Mary Doane

Mine Safety Appliances Company (MSA), telephone number, (412) 967-3151
Attention, John Hierbaum

Ocenco Incorporated. telephone number, (262) 947-9000
Attention, Richard Vanderveer

If it is not possible to replace or have repaired all CSE SR-100 SCSRs manufactured prior to June 7, 1994, immediately, users should consider making additional SCSR devices available in the work area to provide workers with access to more than one device for use in the event of an emergency.

If you have any questions, please contact MSHA at (412) 386-6923 or NIOSH at 1-800-35NIOSH.

Sincerely yours,

Richard W. Metzler, Chief
Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institute for Occupation
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February 14, 2000

LETTER TO ALL RESPIRATOR MANUFACTURERS

The National Institute for Occupational Safety and Health (NIOSH) is announcing a meeting for all respirator manufacturers to be held at the NIOSH facility located at 1095 Willowdale Road, Morgantown, West Virginia, Room L-1BCD on March 22, 2000. An agenda is being developed which will include the following items:

1. Application Log In Time
2. Management of Errors in Applications
3. Treatment of Application Failures
4. Simplified Drawing Package Requirements
5. Application Appeals Process
6. Improving the Application Instructions
7. Module Highlights

Additional time will be provided after the meeting on March 23, 2000, to allow manufacturers with additional questions to meet individually with Respirator Branch staff. All manufacturer representatives, manufacturer application preparers and other interested parties are welcome to attend.

Please respond via the attached fax form by March 10, 2000.

Enclosed please find a list of local hotels in the Morgantown area; if you cannot attend, we will be glad to send you copies of the materials distributed at the meeting after its conclusion.

Sincerely yours,

Ray Wells
Deputy Chief, Respirator Branch
Division of Respirator Disease Studies

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 16, 2000

LETTER TO ALL MANUFACTURERS

SUBJECT: Approval Label Change

Gas masks and chemical cartridge respirators have generally not been approved for use against gases and vapors with poor warning properties under 42 CFR Part 84 except where their use is permitted by MSHA or OSHA standards (42 CFR §§ 84.110 note 2, 84.190 note 1) or they are equipped with adequate end-of-service-life indicators (ESLI). The NIOSH requirements for approval of a respirator equipped with an ESLI were published in the Federal Register on July 19,1984 (49 FR 29270).

The Institute issued a policy statement on August 4, 1999, endorsing OSHA's new respiratory protection standard, 29 CFR 1910.134 (63 FR 1152) that permits the use of respirators for protection against gases and vapors provided that the respirator is equipped with an ESLI certified by NIOSH, or if there is no ESLI appropriate for the condition in the employer's workplace, a change schedule for canisters and cartridges. NIOSH is now requiring a change to "Caution H" listed on the NIOSH approval labels and to the user instructions in order to be consistent with the August 4, 1999, Institute policy statement and acceptable under the OSHA standard.

NIOSH will require respirator approval labels to use the new "Caution H" which states "H: Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs." User instructions should also reflect this change.

Effective October 1, 2000, NIOSH will require applications to use the new "Caution H" where new or modified gas mask and chemical cartridge respirator approval labels are issued. User instructions for these applications should also reflect this change.

Effective July 1, 2001, all NIOSH approval labels and user instructions for gas masks and chemical cartridge respirators which are sold and shipped by manufacturers shall reflect this change to "Caution H". Manufacturers need not submit applications or otherwise notify NIOSH where the change to "Caution H" is the only change being made to the approved configurations.

Any questions pertaining to this issue should be directed to the NIOSH Respirator Branch at 304-285-5907.

Sincerely yours,

Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 26, 2000

LETTER TO ALL INTERESTED PARTIES

Notice of Stakeholder and Public Meetings Concerning Quality Assurance and Administrative Requirements for Approval of Respirators

The Respirator Branch, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH) would like to meet with interested stakeholders about issues and concerns related to quality assurance and administrative requirements for the approval of respirators. NIOSH is developing a proposed rule to update the present quality assurance and administrative requirements which the Institute hopes to publish in early 2001. NIOSH is seeking individual input from its stakeholders for this process and will, therefore, hold two public meetings in mid-August 2000. In addition, NIOSH stakeholders are invited to schedule one-on-one meetings with Institute representatives. The purpose of the public meetings, as well as the additional stakeholder meetings, is to provide opportunities for an exchange of information between NIOSH and the respirator manufacturers, industry representatives, labor representatives, and others involved with respiratory protection.

NIOSH will hold two Public Meetings in mid-August 2000:

August 8th – Arlington, Virginia
Quality Hotel & Suites, Courthouse Plaza, Jefferson Room
1200 North Courthouse Rd.
Arlington, VA 22201
Phone: (888) 987-2555 or (703) 524-4000
To receive the NIOSH group rate of $118.00, call by July 21st.

August 16th – San Francisco, California
Embassy Suites, Ambassador Ballroom
150 Anza Boulevard
Burlingame, CA 94010
Phone: (650) 340-0327
To receive the NIOSH group rate of $164.00, call by July 24th.

These meetings will be open to the public, limited only by the space available; advance registration is not required. However, any attendee wishing to make a presentation will need to inform NIOSH of this intent by July 31, 2000. A Federal Register Notice will be published to publicly announce these meetings.

NIOSH also invites all interested parties to schedule individual stakeholder meetings with the Respirator Branch before the end of August 2000 to discuss the quality assurance and administrative improvement concepts. Meetings can be held at the stakeholders' facilities or at NIOSH, Morgantown, West Virginia. For each meeting, NIOSH will provide an overview of the quality assurance and administrative concepts under consideration. Participants will be given an opportunity to ask questions and submit verbal and written comments they wish to have included in the regulatory record and thereby provide input into potential changes to the applicable regulations. NIOSH will prepare a summary of each of these meetings which will be placed in the regulatory docket.

Requests to schedule Stakeholder Meetings can be made by email, fax or letter. Email can be sent to either the Respirator Branch (respcert@cdc.gov) or the NIOSH Docket Office (niocindocket@cdc.gov). Faxes can be sent to either the Respirator Branch [(304) 285-6030] or the NIOSH Docket Office [(513) 533-8285]. Letters can be mailed to either the Respirator Branch (NIOSH, Attn: Matt Bowyer or Roland Berry Ann, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888) or the NIOSH Docket Office (NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226)

JUSTIFICATION FOR PROPOSED CHANGES

NIOSH has not updated the administrative and quality assurance requirements for the approval of respiratory protective devices under 42 CFR Part 84 since the early 1970s.

Quality Assurance Requirements

NIOSH is in the process of developing a proposed rule to amend its existing requirements for quality control plans, site audits, and product audits and to implement quality assurance requirements consistent with international quality system standards.

An essential part of the NIOSH respirator approval requirements is the manufacturer's implementation of quality controls to limit the variability in the production of approved units. These quality controls are chosen and implemented to measure variations of specific parameters within the manufacturing process. The present regulation does not contain adequate requirements to determine that the approval holder is meeting this obligation.

The manufacturing process must be monitored to verify the adequacy and effectiveness of the implemented quality controls. There are basically three components used for monitoring. First, the process must be monitored to verify that the controls are followed. This is accomplished by in-plant audits. Second, produced units must be checked via product audits to ensure that the controlled manufacturing process produces respirators that perform as expected. Third, problem investigations must be performed for any units where user complaints are reported. All three of these components can and should be performed by the approval holder as well as the approving authority (NIOSH).

Historically, the quality monitoring NIOSH could perform has been severely limited. Nonetheless, the Institute has identified a significant number of critical findings which required stop-sale or recall requests. During the past three years, we have conducted site audits at approximately 20 facilities per year and found nonconformances in approximately 57% of these audits. Fifteen percent of these nonconformances (6 audits) were of a critical nature requiring a stop-sale letter to be issued. Other indicators of the need for increased oversight: 1) While less than 1% of the approvals were subject to a product audit, 40% of these identified a nonconformance, of which, 5% required a recall/retrofit. 2) While users have only filed an annual average of 40 complaints concerning respirator performance over the past two years, twenty-three percent (18) of them required corrective action. Nine of these involved a recall and/or retrofit of thousands of respirators. We believe it is important to strengthen the manufacturers' obligations and NIOSH's ability to perform these audits.

User Fees

Existing user fees for obtaining a NIOSH approval were based on the examination, inspection and testing of respiratory protective devices to evaluate their conformance to the regulations. These fees do not reflect current government costs for providing these services. The basis for the current fee charges is outdated: collected fees representing only 20% of actual costs incurred for the approval processing activity. Moreover, the present fee schedule does not reflect many of the services NIOSH provides to approval holders.

SUMMARY OF CONCEPTS UNDER CONSIDERATION

NIOSH has not determined the final content of its proposed rulemaking. The Institute is considering the regulatory actions listed below and is specifically asking for comments on these proposed actions. We also welcome comments on additional areas that stakeholders want to address.

NIOSH is in the process of developing the following proposals:

1) That quality assurance requirements for approval holders' manufacturing process be consistent with international standards - specifically the International Organization for Standards (ISO) 9000 guidelines. These standards would be supplemented by revised respirator specific quality measures, such as quality control plans and product improvement procedures.

2) That new quality requirements be established; e.g., mandatory pre-approval audits for new manufacturing sites, more stringent quality sampling plans, critical classification of defects for all respirator types, and records retention schedules.

3) That NIOSH's quality monitoring activities be enhanced by: increasing the frequency of both site and product audits; requiring approval holders to supply free product audit samples for product audits; requiring approval holders to conduct self audits of their products and convey

results to NIOSH; accepting ISO certification in lieu of a NIOSH performed site audit; employing contract laboratories to do certain tests for the approval program; and requiring approval holders to report all customer complaints and non-compliance findings of a serious nature to NIOSH.

4) That a new fee structure be implemented to recover costs of approval application processing (approximately a 2.5 times increase over the current application fees); approval records maintenance (a new annual fee of approximately $36 per approval); and audit costs [a new charge computed according to the hourly rate of government personnel (approximately $50 per hour plus expenses)] for the chargeable services received by the applicants or approval holders.

In addition, NIOSH is requesting information and comments as to how respirator labels could be improved.

For further information, please contact Matt Bowyer or Roland Berry Ann, NIOSH, at 304-285-5907.

Sincerely yours,

for Richard W. Metzler
Chief, Respirator Branch
Division of Respirator Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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June 30, 2000

LETTER TO TESTING LABORATORIES AND ACCREDITED REGISTRAR ACCREDITATION BOARD AUDITORS

Subject: Meeting Announcement Concerning the Utilization of Private Sector Laboratories and Auditors as part of the Quality Assurance and Administrative Improvement Concepts for the Approval of Respirators

The Respirator Branch (RB) of the Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH) would like to meet with interested testing laboratories and Registrar Accreditation Board (RAB) accredited auditors on issues and concerns related to quality assurance and administrative requirements for the approval of respirators. NIOSH is in the process of developing a proposed rule to update the present quality assurance and administrative requirements which it hopes to publish early 2001. The agency is seeking individual input from its stakeholders for this process. To get this input, NIOSH will be holding two public meetings in mid August 2000. In addition, NIOSH is inviting all interested laboratories and auditors to attend meetings at NIOSH, in Morgantown, West Virginia, on July 25-26, 2000. The purpose of the public meetings, as well as the laboratory and auditor specific meetings, is to provide an opportunity for an exchange of information between the Agency and the respirator manufacturers, industry representatives, labor representatives, and others involved with respiratory protection.

The Public Meetings will be held for one day each, on August 8, 2000, in the Washington, D.C. and on August 16, 2000, in the San Francisco, California areas. They will be open to the public, limited only by the space available. Advance registration for the Public Meetings is not required. However, any attendee wishing to make a presentation at one of these public meetings will need to inform NIOSH of this intent by July 31, 2000. The forthcoming Federal Register Notice provides additional information on these meetings.

NIOSH invites all interested testing laboratories to attend a meeting on July 25, 2000, at NIOSH, 1095 Willowdale Rd, Morgantown, West Virginia, Room L-2A, at 8:30 a.m. to 11:30 a.m. The afternoon will be made available for anyone interested in one-on-one sessions. These sessions will be time limited and will be on a first-come first-serve basis.

NIOSH invites all interested auditors to attend a meeting on July 26, 2000, at NIOSH, 1095 Willowdale Road, Morgantown, West Virginia, Room L-1C & D, 8:30 a.m. to 11:30 a.m. The afternoon will be made available for anyone interested in one-on-one sessions. These sessions will be time limited and will be on a first-come first-serve basis.

For each meeting, NIOSH will provide an overview of the quality assurance and administrative concepts under consideration. Participants will be given an opportunity to ask questions, as well as submit verbal and written comments they wish to have included in the regulatory record to provide input into potential changes to the applicable regulations. NIOSH will prepare a summary of each of these meetings which will be placed in the regulatory docket.

NIOSH is requesting that those Laboratories and/or Auditors planning to attend one or both meetings please notify Matt Bowyer or Roland Berry Ann at (304) 285-5907 or fax (304) 285-6030 by July 19, 2000.

Laboratories and Auditors may provide comments to the docket via email, fax or letter. Email can be sent to either the Respirator Branch (respcert@cdc.gov) or the NIOSH Docket Office (niocindocket@cdc.gov). Faxes can be sent to either the Respirator Branch [(304) 285-6030] or the NIOSH Docket Office [(513) 533-8285]. Letters can be mailed to either the Respirator Branch (NIOSH, Attn. Matt Bowyer or Roland Berry Ann, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888) or the NIOSH Docket Office (NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226)

Justification for Change:

NIOSH has not updated the administrative and quality assurance requirements for the approval of respiratory protective devices under 42 CFR Part 84 since the early 1970s.

1. Quality Assurance Requirements

NIOSH is considering proposing to amend its existing requirements for quality control plans, site audits, and product audits and to implement quality assurance requirements consistent with international quality system standards.

An essential part of the NIOSH respirator approval is the manufacturer's implementation of quality controls to limit the variability in the production of approved units. These quality controls are chosen and implemented to measure variations of specific parameters within the manufacturing process. The present regulation does not contain adequate requirements to determine that the approval holder is meeting this obligation.

The manufacturing process must be monitored to verify the adequacy and effectiveness of quality controls put in place. There are basically three components used for this monitoring. First, the process must be monitored to verify that the planned controls are in place and being followed. This is accomplished by in-plant audits. Second, produced units must be checked via product audits to assure that the controlled manufacturing process produces respirators that perform as expected. Third, problem investigations must be performed for any units where user complaints are reported. All three of these components can and should be performed by the approval holder as well as the approving authority (NIOSH).

NIOSH has historically been severely limited in the amount of quality monitoring that we could perform. Even with this limited monitoring, NIOSH has identified a significant number of critical findings requiring stop sale or recall requests. NIOSH has conducted site audits at approximately 20 facilities per year for the past three years. NIOSH has found nonconformances in approximately 57% of these audits. In addition, 15% of these nonconformance (6 audits) were of a critical nature requiring a stop-sale letter to be issued. Other indicators of the need for greater oversight are: 1) less than 1% of the approvals were subject to a product audit. However, 40% of these identified a nonconformance, of which, 5% require a recall/retrofit, and 2) the Institute averages 40 field problem investigations per year, of which 45% (18 investigations) required corrective action. Of these, 8 involved a recall and 1 required a stop-sale request. We believe it is important to strengthen the manufacturers' obligations and NIOSH's ability to perform these audits.

2. Fees

The existing user fees for obtaining a NIOSH approval were based on the examination, inspection and testing of respiratory protective devices to evaluate their conformance to the regulation. These fees do not reflect the current cost to the government for providing these services. The basis for the present fee charges is outdated, with collected fees representing only 20% of actual costs incurred today for the approval processing activity. Moreover, the present fee schedule does not reflect many of the services NIOSH provides to approval holders.

SUMMARY OF CONCEPTS UNDER CONSIDERATION:

We want to emphasize that NIOSH has not determined the final content of its proposed rulemaking. However, the agency is considering the regulatory actions listed below. NIOSH is specifically asking for comments on these proposed actions, but would also welcome comments on additional areas that the stakeholders believe may need to be addressed.

NIOSH is considering:

1. Proposing quality assurance requirements for the approval holder's manufacturing process that are consistent with international standards, specifically the International Organization for Standards (ISO) 9000 guidelines. These international standards would be supplemented by revised respirator specific quality measures, such as quality control plans and product improvement procedures.

2. Proposing new quality requirements, such as, mandatory pre-approval audits for new manufacturing sites. more stringent quality sampling plans, critical classification of defects for all type respirators, and records retention schedules.

3. Proposing to enhance quality monitoring activities by NIOSH, by increasing the frequency of both site and product audits, requiring an approval holder to supply free product audit samples for product audits, requiring approval holders to conduct self audits

of their products and present those results to NIOSH, accepting ISO certification in lieu of a NIOSH performed site audit, employing contract laboratories to do certain tests for the approval program, and requiring approval holder to report all customer complaints and non-compliance findings of a serious nature to NIOSH.

4. Implementing a new fee structure to recover costs of approval application processing (approximately a 2.5 times increase over the current application fees), approval records maintenance (a new annual fee approximately $36 per approval), and auditing costs (a new charge computed based on the hourly rate of government personnel (approximately $50 per hour) plus expenses) for the chargeable services received by the applicant or approval holder.

In addition, NIOSH is requesting information and comments to improve respirator labels.

For further information, please contact Matt Bowyer or Roland Berry Ann, NIOSH, at (304) 285-5907.

Sincerely yours,

for Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 304-285-5907
Fax: 304-285-6030

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupatio
Safety and Health - ALOSH
1095 Willowdale Road
Morgantown, WV 26505-2888

July 31, 2000

**LETTER TO ALL REGISTRANTS FOR
NIOSH-DOD-OSHA SPONSORED
CHEMICAL AND BIOLOGICAL
RESPIRATORY PROTECTION WORKSHOP**

Enclosed is your copy of the report from the Respiratory Protection Workshop held in Morgantown, West Virginia, on March 10-12, 1999. This Workshop provided a forum for over 140 subject-matter experts representing 63 different emergency responder, fire fighter, domestic preparedness, equipment manufacturing, federal research, and state and federal regulatory organizations. The open discussions of chemical and biological terrorism issues, exchange of information, and forming of new partnerships, each contributed to the success of this Workshop.

Since this Workshop, NIOSH, OSHA, the National Fire Protection Association, and The National Institute for Standards and Technology (NIST) have signed a Memorandum of Understanding to jointing develop standards for chemical, biological, radiological and nuclear (CBRN) counter terrorism equipment (with respirators as the first priority). Multiple Interagency Agreements and Memorandum of Understanding have been signed between NIOSH, NIST, and the U.S. Army Soldiers and Biological and Chemical Command (SBCCOM) to begin development of NIOSH CBRN respiratory protection standards.

In closing, we thank the co-sponsors of this Workshop and the employees, employers and organizations that participated. Your interest, avid participation in discussions, and tenacity to travel through a major winter storm to attend were key to the success of the workshop and our common understanding of the domestic preparedness-related respiratory protection issues.

If you have any questions regarding this issue, please contact John Dower at (304) 285-5954.

Sincerely yours,

Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Telephone: (304) 285-5749
Fax: (304) 285-5861
Email: grw3@cdc.gov

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888

August 22, 2000

LETTER TO ALL INTERESTED PARTIES

The National Institute for Occupational Safety and Health (NIOSH) is holding a meeting to discuss the recurring problems with self contained self rescuers (SCSRs) used for emergency escapes from mines and other workplaces and the immediate measures needed to address these problems. On behalf of the Institute, I am writing to invite your participation in this stakeholders' meeting to be held on September 12, 2000, in the Lincoln Room at the Quality Hotel & Suites, Arlington, Virginia.

As you are aware, NIOSH is in the process of developing a proposed rule to update the performance standards and to develop reliability standards for SCSRs. However, NIOSH believes interim measures are immediately necessary to improve the reliability of the SCSRs now in service and to restore miners' confidence that these life saving devices perform as intended by their design and to certification standards. NIOSH has determined that the present service life plans for these devices must be reexamined and that the non-destructive tests proposed by several manufacturers require further validation. The Institute will present its plan to address these two issues at this meeting.

Because many field devices inspected by NIOSH have exhibited the results of harsh treatment, and data gathered by MSHA show that a substantial number of devices remain in service despite failing visual inspection, the Institute believes that more effective training must be provided to miners. The Institute plans to develop a training program that incorporates elements of proper SCSR handling as well as enhances awareness of the importance of meticulously following manufacturers guidelines for inspecting devices. We will invite discussion as to the training program's content.

We hope to take all significant data and information into consideration in the development of new policies. All interested parties are encouraged to present pertinent information at the meeting and to submit any supporting data directly to the Respirator Branch. Written submissions may be directed to the attention of Robert Stein, NIOSH, Respirator Branch, 1095 Willowdale Road, Morgantown, West Virginia 26505. If anyone submitting additional data wishes to do so in person, please contact Robert Stein at (304) 285-5907 to make arrangements.

I hope you will join with NIOSH in assuring SCSR problems are addressed immediately. We look forward to your participation in this meeting.

Sincerely yours,

Gregory R. Wagner, M.D.
Director
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 304-285-5907
Fax: 304-285-6030

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupatio
Safety and Health - ALOSH
1095 Willowdale Road
Morgantown, WV 26505-2888

September 18, 2000

LETTER TO ALL MANUFACTURERS

Subject: Respirator Application Processing Times

Several manufacturers have expressed concerns over respirator application processing times, especially the times from when manufacturers send applications to when they are actually logged into the NIOSH Respirator Branch system. In response to that request, NIOSH agreed to track the next one hundred applications received after the March 22, 2000, meeting. A total of one hundred applications has now been received and the data is in the attached table.

The data shows that the average time between receipt of the applications at NIOSH and logging the applications into the NIOSH Respirator Branch system was just over three calendar days. Weekends were counted in this data and are indicated in the column titled "Weekend". Please note that the normal NIOSH procedure is to log an application in only after the check and hardware (where applicable) as well as the application are received (i.e. not until the last of the three arrives). The calculated average log-in time, following the normal NIOSH procedure, was about two and a half days.

The data also shows that the average time between the dates listed on the applications and the receipt date of the applications at NIOSH was just over nine days. Again, please note that the normal NIOSH procedure is to consider the application as received only after the check and hardware (where applicable) as well as the application are received. Following the normal NIOSH procedure, the average time was about twelve days.

Three data points were not factored into these averages because they appeared to be the result of incorrectly listed application dates. These data points are footnoted in the table. All other data points were considered valid.

Some common application errors were observed and include:

-File names on application document list do not exactly match file names on disks.
-File name extensions are omitted.
-Applicant assigned reference (AAR) numbers are not consistent throughout the application.
-Revised documents are incorrectly marked as "Previously Submitted".

The cumulative affect of these common application errors take time to correct resulting in application processing delays. However, these errors must be corrected to properly link applications to the appropriate files and to ensure that they stay linked after the applications are completed.

In reviewing the comments given at the All Manufacturers Meeting, there may be two other areas which explain why there may be a perception of occasional but significant delays.

The first area is in the interpretation of "Initial Review Began" which is shown on the NIOSH web site. "Initial Review Began " is when the technical evaluation of an application is started. It is not when the application is received and first logged into the NIOSH Respirator Branch system. The time when an

application is received and first logged into the NIOSH Respirator Branch system is not shown on the NIOSH web page. Depending on the number of applications already in the Initial Review queue, the technical Initial Review may not be started (and the "Initial Review Began" date listed) for several days following receipt of an application.

Due to size and format limitations of the NIOSH web page, the time when an application is received and first logged into the NIOSH system cannot be added unless another field is deleted. But, manufacturers can determine that an application has been received and logged into the NIOSH system by sending a self-addressed stamped post card along with the application. This post card is promptly completed by listing the NIOSH task number (TN) and returned to the manufacturer. Also, since the All Manufacturers Meeting, a NIOSH representative has been calling or E-mailing each application preparer to confirm receipt of an application when the application is logged in and a task number is assigned.

The second area involves corrections. When corrections are received, they are reviewed as quickly as possible after receipt. However, reviewing received corrections to in-house applications can delay starting the review of new applications. Since the certification process is ongoing, the greater the number of corrections to in-house applications, the longer the delays for new applications.

In summary, we have determined that:

-Application package log-in times average approximately three days.
-Application dates to receipt dates average just under ten days.
-The cumulative affect of application errors adds to processing time.
-Calling or E-mailing application preparers to confirm application receipt appears beneficial and will continue.
-Reviewing corrections for in-house applications before starting new applications will inherently result in some delay in reviewing new applications (but is the method preferred by NIOSH).

We hope this information is helpful and remain open to suggestions which may improve our process. If you note any areas that you believe could be improved, please let us know. Thank you for your input.

Sincerely yours,

Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

Enclosure

Application Log-in Data For 100 Projects Received
March - June 2000

Task Number*	Date on Application	Delivery Service Used	Date Shipped from Mfr.	Date Appl. Rec'd @ NIOSH Warehouse	Date Application Rec'd @ RB	Date Fee Rec'd @ RB	Date Hardware Rec'd @ RB	Date Logged into the DEIMS	Days from App Date to App Receipt at NIOSH	Days from App Date to receipt of last item at NIOSH**	Days from App Receipt at NIOSH to Login	Days from receipt of last item to log in at NIOSH**	Weekend	Comments***	Date of Phone Call or Email to MFR (started 4/21/00)***
11443	3/20/00	FED EX	3/29/00	3/30/00	3/30/00	N/A	N/A	3/31/00	10	10	1	1	N		
11444	3/7/00	UPS GROUND	3/28/00	3/30/00	3/30/00	N/A	N/A	4/3/00	23	23	4	4	Y	Application TN-11445 was blank.	
11445	3/7/00	UPS GROUND	3/28/00	3/30/00	3/30/00	N/A	N/A	4/3/00	23	23	4	4	Y		
11446	3/7/00	UPS GROUND	3/28/00	3/30/00	3/30/00	N/A	N/A	4/3/00	23	23	4	4	Y		
11447	3/20/00	UNKNOWN	UNKNOWN	UNKNOWN	3/29/00	3/29/00	3/27/00	4/4/00	9	9	6	6	Y	Mix-up on hardware--Not labeled properly.	
11448	3/20/00	UNKNOWN	UNKNOWN	UNKNOWN	3/29/00	3/29/00	3/27/00	4/4/00	9	9	6	6	Y	Same as above	
11449	3/20/00	UNKNOWN	UNKNOWN	UNKNOWN	3/29/00	3/29/00	3/27/00	4/4/00	9	9	6	6	Y	Same as above	
11450	3/31/00	E-MAIL	4/4/00	N/A	4/4/00	N/A	N/A	4/5/00	4	4	1	1	N		
11451	3/28/00	US MAIL	3/29/00	ND	3/31/00	3/31/00	3/31/00	4/5/00	3	3	5	5	Y		
11453	3/24/00	US MAIL	3/27/00	ND	3/31/00	3/31/00	3/29/00	4/5/00	7	7	5	5	Y		
11454	3/30/00	FED EX	3/31/00	4/3/00	4/3/00	4/3/00	4/3/00	4/5/00	4	4	2	2	N		
11455	3/31/00	UPS	3/31/00	4/3/00	4/3/00	4/3/00	4/3/00	4/5/00	3	3	2	2	N		
11456	3/30/00	US POSTAL	3/31/00	ND	4/4/00	N/A	N/A	4/5/00	5	5	1	1	N		
11457	3/29/00	FED EX	4/3/00	4/4/00	4/4/00	4/4/00	4/4/00	4/6/00	6	6	2	2	N		
11458	3/29/00	FED EX	4/3/00	4/4/00	4/4/00	4/4/00	4/4/00	4/6/00	6	6	2	2	N		
11459	3/29/00	FED EX	4/3/00	4/4/00	4/4/00	4/4/00	4/4/00	4/6/00	6	6	2	2	N		
11460	2/8/00	FED EX	4/3/00	4/4/00	4/4/00	N/A	N/A	4/7/00	56	56	3	3	N		
11461	3/31/00	US MAIL	3/31/00	ND	4/5/00	N/A	N/A	4/7/00	5	5	2	2	N		
11462	3/31/00	US MAIL	3/31/00	ND	4/5/00	N/A	N/A	4/7/00	5	5	2	2	N		
11463	4/4/00	FED EX	4/5/00	4/6/00	4/6/00	N/A	N/A	4/7/00	2	2	1	1	N		
11464	4/4/00	US MAIL	4/6/00	ND	4/10/00	N/A	N/A	4/11/00	6	6	1	1	N		
11465	3/26/00	E-MAIL	4/6/00	N/A	4/6/00	4/5/00	4/5/00	4/11/00	9	9	5	5	Y		
11466	3/9/00	E-MAIL	4/6/00	N/A	4/10/00	4/5/00	4/5/00	4/11/00	32	32	1	1	N	File names incorrect, extensions missing, files missing.	
11467	3/9/00	E-MAIL	4/6/00	N/A	4/10/00	4/5/00	4/5/00	4/11/00	32	32	1	1	N	Same as above	
11468	4/6/00	FED EX	4/7/00	4/10/00	4/10/00	4/10/00	4/10/00	4/12/00	4	4	2	2	N		
11469	3/27/00	FED EX	4/7/00	4/10/00	4/10/00	N/A	N/A	4/12/00	14	14	2	2	N		

Application Log-in Data For 100 Projects Received
March - June 2000

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11471	7/14/00	E-MAIL	4/17/00	N/A	4/17/00	N/A	N/A	4/18/00	-88**	-88**	1	1	N	Application date is incorrect.	4/21/00 E-mail
11475	3/25/00	FED EX	4/17/00	4/18/00	4/18/00	N/A	N/A	4/19/00	24	24	1	1	N		4/21/00
11476	4/12/00	FED EX	4/12/00	4/13/00	4/13/00	4/13/00	4/13/00	4/19/00	1	1	6	6	Y		4/21/00
11477	4/6/00	DPE INT'L	UNKNOWN	UNKNOWN	4/13/00	4/13/00	4/13/00	4/19/00	7	7	6	6	Y	Same as above	4/21/00 E-mail
11478	4/6/00	DPE INT'L	UNKNOWN	UNKNOWN	4/13/00	4/13/00	4/13/00	4/19/00	7	7	6	6	Y	Same as above	4/21/00 E-mail
11479	4/6/00	DPE INT'L	UNKNOWN	UNKNOWN	4/13/00	4/13/00	4/13/00	4/19/00	7	7	6	6	Y	Same as above	4/21/00 E-mail
11480	3/29/00	UPS	4/17/00	4/18/00	4/18/00	4/18/00	4/18/00	4/20/00	20	20	2	2	N		4/20/00
11481	4/4/00	FED EX	4/20/00	4/21/00	4/21/00	N/A	N/A	4/24/00	17	17	3	3	Y		4/25/00
11482	1/3/99	FED EX	4/19/00	4/20/00	4/20/00	4/20/00	4/19/00	4/24/00	473**	473**	4	4	Y	No file extensions/one file missing/file name incorrect	4/25/00
11483	4/7/00	FED EX	4/20/00	4/21/00	4/21/00	NA	NA	4/24/00	14	14	3	3	Y		4/25/00
11484	4/24/00	E-MAIL	4/24/00	N/A	4/24/00	NA	NA	4/25/00	0	0	1	1	N		4/26/00
11488	4/20/00	FED EX	4/25/00	4/26/00	4/26/00	N/A	N/A	4/27/00	6	6	1	1	N	No file extensions	4/27/00
11489	4/17/00	UPS	4/20/00	4/21/00	4/21/00	4/21/00	4/27/00	4/28/00	4	10	7	1	Y		4/28/00
11490	4/17/00	UPS	4/20/00	4/21/00	4/21/00	4/21/00	4/27/00	4/28/00	4	10	7	1	Y		
11491	4/17/00	UPS	4/20/00	4/21/00	4/21/00	4/21/00	4/27/00	4/28/00	4	10	7	1	Y		
11492	4/17/00	UPS	4/20/00	4/21/00	4/21/00	4/21/00	4/27/00	4/28/00	4	10	7	1	Y		
11493	4/5/00	PRIORITY MAIL	4/18/00	ND	4/21/00	4/21/00	4/27/00	5/1/00	16	22	10	4	Y		5/1/00
11494	4/27/00	FED EX	4/27/00	4/28/00	4/28/00	4/28/00	4/28/00	5/3/00	1	1	5	5	Y		5/3/00
11495	4/24/00	UNKNOWN	UNKNOWN	UNKNOWN	5/1/00	5/1/00	5/2/00	5/3/00	7	8	2	1	N		5/3/00
11496	4/24/00	UNKNOWN	UNKNOWN	UNKNOWN	5/1/00	5/1/00	5/2/00	5/3/00	7	8	2	1	N		
11500	4/26/00	US MAIL	4/26/00	ND	5/1/00	5/1/00	5/2/00	5/3/00	5	6	2	1	N		5/3/00
11504	3/5/00	E-MAIL	5/4/00	N/A	5/5/00	5/8/00	N/A	5/9/00	61	64	4	1	Y	Computer Down 5/5/00--5/8/00	5/11/00
11505	5/1/00	FED EX	5/4/00	5/5/00	5/5/00	N/A	N/A	5/9/00	4	4	4	4	Y	Computer Down 5/5/00--5/8/00	5/11/00
11508	5/8/00	FED EX	5/9/00	5/10/00	5/10/00	N/A	N/A	5/11/00	2	2	1	1	N	No Extensions on file names	5/11/00
11513	5/8/00	FED EX	5/9/00	5/10/00	5/10/00	5/10/00	5/10/00	5/12/00	2	2	2	2	N		5/15/00 e-mail
11514	5/8/00	FED EX	5/9/00	5/10/00	5/10/00	5/10/00	5/10/00	5/12/00	2	2	2	2	N		
11515	4/10/00	UPS	5/11/00	5/12/00	5/12/00	5/4/00	5/8/00	5/15/00	32	32	3	3	Y	Had to request new application	5/18/00

Application Log-in Data For 100 Projects Received
March - June 2000

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11516	5/12/00	FED EX	5/12/00	5/15/00	5/16/00	N/A	N/A	5/17/00	3	3	2	2	N	DEIMS down 5/16 - 5/17/00	5/18/00
11517	5/11/00	UPS	ND	ND	5/15/00	5/15/00	5/15/00	5/17/00	4	4	2	2	N	DEIMS down 5/16 - 5/17/00	5/18/00
11520	5/11/00	FED EX	5/12/00	5/15/00	5/15/00	5/15/00	5/15/00	5/18/00	4	4	3	3	N	DEIMS down 5/16 - 5/17/00	5/18/00
11521	5/15/00	FED EX	5/17/00	5/18/00	5/18/00	5/18/00	5/18/00	5/19/00	3	3	1	1	N		5/19/00
11524	5/1/00	UPS	5/18/00	5/19/00	5/19/00	5/15/00	5/15/00	5/22/00	18	18	3	3	Y	First disks hand delivered 5/15/00; but were returned due to virus	5/22/00
11525	5/1/00	UPS	5/18/00	5/19/00	5/19/00	5/15/00	5/15/00	5/22/00	18	18	3	3	Y	Same as above	5/22/00
11527	5/19/00	US MAIL	ND	ND	5/22/00	5/22/00	5/26/00	5/24/00	3	7	2	1	N	Inadvertantly log in prior to hardware receipt.	5/31/00
11529	10/26/00	US MAIL	5/20/00	ND	5/24/00	N/A	N/A	5/26/00	212	212	1	1	N		5/26/00
11530	5/5/00	UPS	5/15/00	5/16/00	5/16/00	5/16/00	5/24/00	5/25/00	11	19	9	1	Y		5/26/00
11531	5/8/00	UPS	5/17/00	5/18/00	5/18/00	5/18/00	5/24/00	5/25/00	10	16	7	1	Y		5/25/00
11532	5/22/00	US MAIL	5/22/00	ND	5/26/00	N/A	N/A	5/30/00	4	4	4	4	Y	Memorial Day Holiday	5/30/00
11533	5/12/00	US MAIL	5/22/00	ND	5/26/00	5/26/00	5/23/00	5/30/00	14	14	4	4	Y	Memorial Day Holiday	5/30/00
11538	5/26/00	E-MAIL	5/26/00	N/A	5/30/00	N/A	N/A	5/30/00	4	4	0	0	N		5/30/00
11539	5/24/00	US MAIL	5/25/00	ND	5/30/00	N/A	N/A	5/31/00	6	6	1	1	N		5/31/00
11540	5/26/00	US MAIL	5/25/00	ND	5/30/00	5/30/00	5/30/00	5/31/00	4	4	1	1	N		5/31/00
11542	5/24/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/30/00	5/31/00	6	6	1	1	N		5/31/00
11543	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Missing files; incorrect file names	6/2/00
11544	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11545	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11546	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11547	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11548	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11549	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11550	5/22/00	FED EX	5/26/00	5/30/00	5/30/00	5/30/00	5/31/00	6/2/00	8	9	3	2	N	Same as above	6/2/00
11551	5/25/00	UPS	6/1/00	6/2/00	6/2/00	6/2/00	6/2/00	6/6/00	8	8	4	4	Y	File names incorrect; Drawings won't open	6/6/00
11552	6/1/00	UPS	6/2/00	6/5/00	6/5/00	6/5/00	6/5/00	6/7/00	4	4	2	2	N	Could not read drawings	6/8/00

Application Log-in Data For 100 Projects Received
March - June 2000

Task Number*	Date on Application	Delivery Service Used	Date Shipped from Mfr.	Date Appl. Rec'd @ NIOSH Warehouse	Date Application Rec'd @ RB	Date Fee Rec'd @ RB	Date Hardware Rec'd @ RB	Date Logged into the DEIMS	Days from App Date to App Receipt at NIOSH	Days from App Date to receipt of last item at NIOSH***	Days from App Receipt at NIOSH to Login	Days from receipt of last item to log in at NIOSH***	Weekend	Comments****	Date of Phone Call or Email to MFR (started 4/21/00)****
11553	5/30/00	FED EX	5/31/00	6/1/00	6/1/00	6/1/00	6/5/00	6/8/00	2	6	7	3	Y	previously issued; Used AutoCad 2000	6/8/00
11554	6/1/00	US MAIL	6/1/00	ND	6/6/00	6/6/00	6/6/00	6/9/00	4	4	4	4	Y		6/12/00
11555	5/31/00	PRIORITY MAIL	6/1/00	ND	6/7/00	N/A	N/A	6/12/00	7	7	5	5	Y		6/12/00
11556	6/2/00	US MAIL	6/5/00	ND	6/8/00	6/9/00	6/6/00	6/13/00	7	7	4	4	Y	Converted QRK Files	6/13/00
11557	5/25/00	UPS	6/7/00	6/8/00	6/9/00	6/9/00	6/8/00	6/13/00	15	15	4	4	Y	Mfr Ref No. inconsistent.	6/14/00
11558	5/25/00	UPS	6/7/00	6/8/00	6/9/00	6/9/00	6/8/00	6/14/00	15	15	5	5	Y		6/14/00
11559	6/7/00	UPS	6/14/00	6/15/00	6/15/00	6/15/00	6/15/00	6/16/00	8	8	1	1	N		6/16/00
11560	6/13/00	FED EX	6/14/00	6/16/00	6/16/00	6/16/00	6/15/00	6/19/00	3	3	3	3	Y	File names did not have extensions.	6/20/00
11561	6/15/00	UPS	6/15/00	6/16/00	6/16/00	6/16/00	6/16/00	6/20/00	1	1	4	4	Y	Could not read drawings	6/20/00
11562	6/15/00	UPS	6/15/00	6/16/00	6/16/00	6/16/00	6/16/00	6/20/00	1	1	4	4	Y	Could not read drawings	6/20/00
11564	5/15/00	FED EX	6/9/00	6/12/00	6/20/00	N/A	N/A	6/20/00	36	36	0	0	N	Disk received 6/12; new app requested, received 6/20	6/20/00
11565	6/12/00	FED EX	6/16/00	6/19/00	6/19/00	6/19/00	6/20/00	6/21/00	7	8	2	1	N		6/21/00
11566	6/12/00	FED EX	6/16/00	6/19/00	6/19/00	6/19/00	6/20/00	6/21/00	7	8	2	1	N		6/21/00
11567	6/12/00	FED EX	6/16/00	6/19/00	6/19/00	6/19/00	6/20/00	6/21/00	7	8	2	1	N		6/21/00
11568	6/12/00	FED EX	6/16/00	6/19/00	6/19/00	6/19/00	6/20/00	6/21/00	7	8	2	1	N		6/21/00
11570	6/15/00	FED EX	6/19/00	6/20/00	6/20/00	6/20/00	6/20/00	6/22/00	5	5	2	2	N		6/23/00
11571	6/19/00	UPS	6/20/00	6/21/00	6/21/00	6/21/00	6/21/00	6/23/00	2	2	2	2	N		6/23/00
11573	6/21/00	E-MAIL	N/A	N/A	6/22/00	N/A	N/A	6/23/00	1	1	1	1	N		6/23/00
11574	6/15/00	FED EX	6/21/00	6/22/00	6/22/00	6/22/00	6/23/00	6/26/00	7	8	4	3	Y	One file had to be sent again by email.	6/26/00
11575	6/21/00	FED EX	6/21/00	6/22/00	6/22/00	N/A	N/A	6/26/00	1	1	4	4	Y		6/26/00
11576	6/24/00	E-MAIL	6/23/00	N/A	6/23/00	N/A	N/A	6/26/00	-1**	-1**	3	3	Y		6/26/00
Average Time:									9 32	12 24	3 17	2 49			

* Missing task numbers are audits

** Not factored into averages

*** Last of check, hardware, or application to arrive as applicable

**** Those grouped together arrived together

N/A Not applicable

ND Not determined

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 304-285-5907
Fax: 304-285-6030

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupation
Safety and Health - ALOSH
1095 Willowdale Road
Morgantown, WV 26505-2888

November 15, 2000

LETTER TO ALL MANUFACTURERS

Subject: Attachment of Headband Straps on Filtering Facepiece Respirators

Since April 1, 1997, the NIOSH position regarding punctures caused by staples has been: "Any filtering facepiece exhibiting holes around staples, in the breathing zone, through which light can be clearly observed shall be rejected. The justification for this rejection is that these holes are large enough to easily allow penetration of respirable particulates." Manufacturers have been required to institute quality control measures to reduce the size of punctures caused by staples so visible light will not pass.

Several product audits and recent research conducted by manufacturers and NIOSH have caused NIOSH to reconsider this policy. The research has shown that filtering facepiece respirators containing small punctures caused by staples, even punctures large enough to pass light, can still meet the maximum penetration requirement specified in 42 CFR, Part 84 for which these products were approved. Conversely, product audits have shown that sonic welds used to fasten straps can cause the respirator to fail to meet the maximum penetration requirement specified in 42 CFR, Part 84 for which these products were approved. NIOSH has considered the new data and is implementing a change in interpretation incorporating the new perspective on the impact of all fastenings in filtering facepieces.

NIOSH will accept applications for approval of filtering facepiece respirators with fastenings that attach headband straps within the breathing zone, provided the applicant's quality system includes controls to assure the fastenings do not prevent the respirator from meeting the maximum penetration requirement specified in 42 CFR, Part 84.

This requirement can be met one of two ways.

(1) For designs where the strap attachments are always placed on sealed edges or otherwise obviously outside the breathing zone (for example. on a tab), the fastening procedure/ process is to be classified as a Major B characteristic in the Quality Control Plan.

(2) For designs where the strap attachments are not always placed on sealed edges or not otherwise obviously outside the breathing zone, the fastening procedure/process is to be classified as a Major A characteristic in the Quality Control Plan. Test data are to be

included with the application demonstrating any accepted fastenings in the breathing zone do not prevent the respirator from meeting the maximum penetration requirement specified in 42 CFR, Part 84 for which the respirator is approved.

When the respirator design includes the placement of staples within the breathing zone (option (2) above), the user instructions shall also be required to include information explaining the acceptability of punctures due to the stapling process. In conjunction with the existing use conditions that limit filter use to consideration of hygiene, damage and breathing resistance, the user instructions shall include statements that: (A) filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred, and (B) enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. The user instructions are also to provide information that the respirator has been tested and small punctures around the staples are normal and do not interfere with the respirator compliance with Part 84 approval requirements.

Sincerely yours,

for Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 304-285-5907
Fax: 304-285-6030

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health - ALOSH
1095 Willowdale Road
Morgantown, WV 26505-2888

November 20, 2000

LETTER TO ALL MANUFACTURERS

Subject: Revisions to the Standard Application Procedures

At the last All-Manufacturers Meeting held in Morgantown, West Virginia, in March 2000, several manufacturers expressed an interest in reviewing and commenting on the next revision to the Standard Application Procedures (SAP) used for the approval of respirators. The National Institute for Occupational Safety and Health (NIOSH or the Institute) has formalized a final draft revision to the SAP and is seeking input from respirator manufacturers, before the document is finalized.

If you would like to participate in the review of this next revision to the SAP, please contact the NIOSH Records Room at 304-285-5907 by December 5, 2000. A copy of the draft SAP along with a copy of the draft cover letter outlining the changes will be express mailed to you. If you choose to participate in this review process, NIOSH requests that all comments be received by December 31, 2000. Comments received after December 31, 2000, will not be considered in this revision to the SAP. Participation in this review process is completely voluntary on your part, but each manufacturer is encouraged to provide comments. A copy of this draft SAP is also being sent to the International Safety Equipment Association (ISEA) for their comment.

In addition to the changes made to the SAP, NIOSH is seeking comments on two related issues:

1. How do manufacturers prefer to receive the final SAP?
   a) Bound document similar to the October 1999 document.
   b) Loose-leafed, 3-hole punched, 8 1/2 X 11 pages.
   c) Download via the NIOSH webpage on the internet.

2. One manufacturer has asked NIOSH to consider changing the required wording for Caution and Limitation J which appears on the NIOSH approval label as follows: *"The NIOSH caution and limitation J (included on all NIOSH approval labels) states that "Failure to properly use and maintain this product could result in injury or death." This statement could be viewed as being not completely in compliance with ANSI Z535.4-1998, Product Safety Signs and Labels, which states that the hazard with the greatest seriousness level should be ordered first in the word message (ANSI Z535.4, section B6). Therefore, this warning would be more correct if it was revised to say: Failure to properly use and maintain this product could result in death or injury."*

   Please comment on the appropriateness of this approval label word change.

Our goal is to have the SAP finalized and distributed to all respirator manufacturers early in 2001. In order to meet this deadline, it is imperative that manufacturers who choose to participate in the review process provide their comments on the SAP revisions, as well as the two numbered items appearing above, to NIOSH by the due date indicated above.

Thank you for your assistance and cooperation in this matter.

Sincerely yours,

Timothy R. Merinar

Timothy R. Merinar
Team Leader
Quality Assurance Team
Respirator Branch
Division of Respiratory Disease Studies

SECTION F - Sample of New and Extension of Approval Application Forms

Detailed Instructions Can Be Found in Section C

Form Approved: OMB No. 0920-0109
Exp. Date: Aug. 31, 2001

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch

NIOSH

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.2] Type of Application: **New**

[C.3] Manufacturer Data:

Does your organization currently hold any NIOSH approvals? ○ Yes ○ No

[C.3] Manufacturer:

Status of Facility:

[C.5] Application Representative:

[C.3] Address:

[C.3] Telephone:

[C.3] FAX:

[C.3] Internet Address:

[C.15] Shipping Number:

[C.4] Manufacturing Site Name, if different from above:

Has your organization submitted a request for approval for any respirator produced at this manufacturing site at any time in the last 3 years? ○ **Yes** ○ **No**

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.6] Date of Application:

[C.2] Type of Application: New

[B.2.4] Previous Task# (if resubmittal): .

[C.7] Type of Product:

[C.8] Is this an amended application? ○ Yes ○ No

[C.12/ C.8] Is this device intended for mine use? ○ Yes ○ No

[C.8] Is the approval of this application dependent upon the approval of an application that is in process? ○ Yes ○ No

If yes, enter the reference number of the application in process?

[C.9] Reason for Application:

[C.10] Approval History:

[C.15] Is testing required? ○ Yes ○ No

If testing is not required, state why:

Do you want test samples returned? ○ Yes ○ No

If no, NIOSH will dispose of samples.

[C.11] Respirator Description:

General Type:

Type of AP Respirator:

Facepiece Type:

Powered?

Type of Fit:

Is this respirator fit-checkable? ○ Yes ○ No

If the respirator is fit-checkable, include fit check instructions. If the fit check procedure requires use of ancillary equipment, provide this equipment with all other hardware submitted for approval testing.

If the respirator contains electrical components, have the components been approved by MSHA for intrinsic safety? ○ Yes ○ No ○ Does not apply

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

Does this respirator have an exhalation valves? ○ Yes ○ No

Does this respirator have an inhalation valves? ○ Yes ○ No

Cartridge or canister?

Number of cartridges or canisters:

Location of cartridge(s) or canister(s):

Does the respirator protect against a single gas or multiple gases?

Is the cartridge or canister replaceable? ○ Yes ○ No

ESLI indicator? ○ Yes ○ No Location of ESLI:

Number of Filters:

Location of Filter:

Is the filter replaceable? ○ Yes ○ No

Comments:

[C.12] **Intended Protection and Safe Design:**

Series and Level of Protection

Gas/Vapor Contaminants

[C.13] **Pre-submission tests that have been performed**

[C.14] **Model Numbers:**

Model Number	Product Trade Name

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.15] Test Samples:

Quantity	Item	Part Number

[C.16] Quality Assurance Documentation:

Title of QA Manual:

Revision:

Date of QA Manual:

Has the QA Manual been previously accepted? ○ Yes ○ No ○ In Process

If in process, under which reference number was the QA Manual previously submitted?

[C.17] Fee Data:

Check Number:

Check Date:

Check Amount:

[C.24] Summary of Related Documents:

Document Type	Description (60 char. or less)
File Name	Program used to create the file

I certify the information contained in this application is correct and that if approved, no further changes will be made to the product(s) without prior written approval of the National Institute for Occupational Safety and Health, Respirator Branch.

Signature of Authorized Representative

Form Approved: OMB No. 0920-0109
Exp. Date: Aug. 31., 2001

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch

NIOSH

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.2] Type of Application: **Extension**

[C.3] Manufacturer Data:

Does your organization currently hold any NIOSH approvals? ○ Yes ○ No

[C.3] Manufacturer:

Status of Facility:

[C.5] Application Representative:

[C.3] Address:

[C.3] Telephone:

[C.3] Internet Address:

[C.3] FAX:

[C.15] Shipping Number:

[C.4] Manufacturing Site Name, if different from above:

Has your organization submitted a request for approval for any respirator produced at this manufacturing site at any time in the last 3 years? ○ **Yes** ○ **No**

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.6] Date of Application:

[C.2] Type of Application: **Extension**

[B.2.4] Previous Task# (if resubmittal):

[C.7] Type of Product:

[C.8] Is this an amended application? ○ Yes ○ No

[C.8] Is this application the result of any type of field problem or non-conforming site or product audit? If yes, enter the related task number. ○ Yes ○ No

Related Task#:

[C.8] Is the approval of this application dependent upon the approval of an application that is in process? ○ Yes ○ No

If yes, enter the reference number of the application in process?

[C.8] Is this request for a modification involving a recall or retrofit program? If yes, include a copy of the Recall/Retrofit Notice to Users. ○ Yes ○ No

[C.9] Reason for Application:

[C.10] Approval History:

[C.15] Is testing required? ○ Yes ○ No

If testing is not required, state why?

Do you want test samples returned? ○ Yes ○ No
If no, NIOSH will dispose of samples.

[C.11] Type of respirator:

Does this modification affect the approval label? ○ Yes ○ No

Does the respirator have an exhalation valve? ○ Yes ○ No ○ n/a

Description of respirator:

[C.12] **Intended Protection and Safe Design:**

Series and Level of Protection

Standard Application Form for the Approval of Respirators

[C.1] Applicant-Assigned Reference Number:

[C.13] **Pre-submission tests that have been performed**

[C.15] **Test Samples:**

Quantity	Item	Part Number

[C.16] **Quality Assurance Documentation:**

Title of QA Manual:

Revision:

Date of QA Manual:

Has the QA Manual been previously accepted? ○ **Yes** ○ **No** ○ **In Process**

If in process, under which reference number was the QA Manual previously submitted?

[C.17] **Fee Data:**

Check Number:

Check Date:

Check Amount:

[C.24] **Summary of Related Documents:**

Document Type	Description (60 char. or less)
File Name	Program used to create the file

I certify the information contained in this application is correct and that if approved, no further changes will be made to the product(s) without prior written approval of the National Institute for Occupational Safety and Health, Respirator Branch.

Signature of Authorized Representative